IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Todd Siegel et al.	**Atty. Docket No.**	084016.00009
Serial No.:	09/ 539,834	**Group Art Unit:**	3721
Filed:	March 31, 2000	**Examiner:**	Sameh Tawfik

Invention: "AUTOMATED SOLID PHARMACEUTICAL PRODUCT PACKAGING MACHINE"

APPEAL BRIEF

I. REAL PARTY IN INTEREST

The real party in interest is Medical Technology Systems, Inc. as a result of transfer of all right, title and interest to the subject matter of this application Serial No. 09/539,834, via the Assignment recorded in the Patent Office in Reel 013635 Frame 0835 on January 8, 2003.

II. RELATED APPEALS AND INTERFERENCES

Applicants and the undersigned are currently unaware of any related appeals and interferences.

III. STATUS OF CLAIMS

The claims currently stand in condition as modified by Amendment C dated June 3, 2003 canceling claims 1-6 and amending claim 7, as well as the Amendment B dated June 11, 2002 adding claims 7-13 and Amendment A dated October 10, 2001, which have all been entered by the Examiner. Accordingly, claims 7-13 are the only claims now pending, and stand in condition as set forth in the attached Appendix of Claims on Appeal.

IV. STATUS OF AMENDMENTS

All Amendments have been entered as noted in the status of claims and none have been filed subsequent to the Amendment dated June 3, 2003. As noted above all Amendments have been entered by the Examiner.

V. SUMMARY OF INVENTION

The present invention is directed to a method for filling solid pharmaceutical product packaging by automatically selectively dispensing one or more solid pharmaceutical products from a plurality of different drug sources into a common funnel. Advantageously, the funnel is moved relative to the product package template cavities in two dimensions or directions of motion such that the funnel is selectively located above desired ones of the product package template cavities. See page 4, lines 5-7. Thereafter, the solid pharmaceutical products located in the plurality of package template cavities are automatically transferred into corresponding cavities of the product package. See page 4, lines 8-12.

In accordance with the preferred exemplary embodiment of the invention, the method is used to preferably simultaneously fill the template and also package the previously selected pharmaceuticals using commercially available canisters to selectively dispense the desired quantity of solid pharmaceutical products into the common funnel. See generally pages 6-9.

This is described in detail with reference to figures 1, 2, and 3 with reference to corresponding written description beginning on page 6, line 1. Page 6 in the first full paragraph describes a system employing a plurality of pharmaceutical dispensing canisters which are capable of selectively dispensing a pre-designated number of solid pharmaceutical products. See page 6, lines 6-11. The canisters are each independently programmable and

can be manipulated via the computer controller 12. The canisters are capable of selecting individual pills regardless of their size or shape. See page 6, lines 11-13.

Each canister is arranged within the pharmaceutical dispensing mechanism to feed a funnel or trough which transmits a solid pharmaceutical product selectively dispensed from one or more of the canisters into a cavity of a product package template 17. This step is repeated for each of the plurality of cavities in the template 17 that corresponds with the cavities in a single sheet or card of cavities in a package that provide a patient's dosing requirements for a given period of time. See page 6, lines 14-19. The template member 17 is selectively moveable through a range of motion defined by an X-Y axis so that each cavity of the template 17 may be selectively positioned beneath the feed mechanism of the pharmaceutical dispensing mechanism 15 for transfer of pharmaceuticals located in the canisters. The dispensing mechanism 15 has a plurality of canisters that are controlled by signals from the computer. See page 6, lines 19-23.

Page 7 in the second full paragraph indicates that each of the cavities of the pharmaceutical product package is capable of holding a volume of solid pharmaceuticals necessary for patient dosing requirements. Once the template 17 containing temporary storage cavities for each combination of drugs has been filled, the template is automatically positioned over a portion of a pharmaceutical product package. A barrier between the cavities in the template 17 and the pharmaceutical product package is moved when the desired number of cavities have been filled and the pharmaceuticals drop into the corresponding product package cavities.

The prior art of record provides not teaching or suggestion whatsoever regarding this advance in the art. More specifically, all previous systems were deficient in that there were

no automated systems for selectively filling a plurality of different dosing cavities with a plurality of different solid pharmaceutical medications for a single patient. Significantly, this resulted in substantial inefficiencies and expenses due to a number of factors. First, managed care facilities now use patient specific packaging that provide all of a patient's prescription drug needs for a given period of time. Consequently, the managed care facility must go through a time consuming process by using individual pharmacists in order to create a package containing a patient's dose of pharmaceuticals for the desired period of time. Additionally, this is disadvantageous because utilizing pharmacists increases risk of incorrect placement of pharmaceuticals in different cavities for the given period of time as well as placement of incorrect pharmaceuticals in the cavities.

Managed care facilities are constantly seeking to reduce risk of administering incorrect pharmaceuticals to patients as well as reduce costs associated with such routine tasks. This is especially important to smaller facilities with limited resources. Some facilities utilize existing packaging machines which typically transfer only individual doses of a single product into a pharmaceutical package. However, such existing systems are ineffective where, as is often the case, different products of different doses must be deposited into individual cavities. As a result of these shortcomings in the prior art, managed care facilities face increased risk of administering incorrect dose or drug to a patient, increased cost of packaging pharmaceuticals, and increased time in preparing the pharmaceutical packaging for their patients.

The present invention overcomes these shortcomings of the prior art and provides a fully automated pharmaceutical packaging machine which is capable of selectively depositing one or more different pharmaceuticals into an individual cavity for each of a plurality of

individual patient product package cavities. The system is fully automated and utilizes commercially available canisters to select individual pills regardless of their size or shape and selectively dispense a pre-designated number of pharmaceutical products. In this manner, the present invention overcomes the dangers and inefficiencies of the prior art systems while simultaneously achieving costs savings.

VI ISSUES PRESENTED FOR REVIEW

I. Whether claims 7-13 are indefinite for failure to particularly point out and distinctly claim the invention.

II. Whether the combination of references asserted by the Examiner (U.S. Patent Nos. 4,490,963 and 4,834,264) provide the requisite teaching or suggestion to render claims 7-10 and 13 invalid as being obvious in light of the prior art.

III. Whether the combination of references asserted by the Examiner (U.S. Patent Nos. 4,490,963 and 6,023,916) provide the requisite teaching or suggestion to render claims 11 and 12 invalid as being obvious in light of the prior art.

VII GROUPING OF CLAIMS

Based on the rejections set forth by the Examiner, Claims 7-10 and 13, stand together and claims 11-12 stand together.

VIII ARGUMENT

Applicant respectfully submits that the prior art references of record, whether considered alone or in combination, fail to either teach or suggest Applicant's presently claimed invention. Applicant notes that the references of record fail to provide any teaching or suggestion whatsoever regarding the movement of the funnel relative to the product

package template cavities in two dimensions or directions to advantageously allow each individual cavity to be selectively filled with one or more pharmaceutical products according to a desired prescription. Therefore, the rejection is improper.

A. Claims 7-13 are Not Indefinite.

Claims 7-13 in the application currently stand rejected as being indefinite for failure to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, in the final office action, the Examiner asserted that the phrase: "...effecting relative motion in at least two directions between the funnel and plurality of product package template cavities..." (Claim 7, lines 4-6) is vague and indefinite. Applicant submits that the claim language would sufficiently indicate to a person of ordinary skill in the art that a motion such as, for example, along an X-Y axis, for motion of the funnel and/or the product package template cavities may be utilized to practice the invention.

Applicants note that the specification describes relative motion for the cavities with respect to the funnel as noted above and thereby directly supports the referenced claim language. In addition to clearly supporting the claim language, the specification ensures that a person of ordinary skill in the art readily understands the meaning of the referenced claim language. More specifically, those skilled in the art will readily appreciate that it is necessary to effect the relative motion between the funnel through which the medications pass and the template cavities in order to provide the ability to selective dispense one or more solid pharmaceutical products selectively into individual cavities. This aspect of the invention is clearly described in the instant specification.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

B. The Cited References, U.S. Patent Nos. 4,490,963 and 4,834,264, Fail to Teach or Suggest the Claimed Invention of Claims 7-13.

Claims 7-10 and 13 in the application currently stand rejected as being obvious in light of the combined teachings of United States Patent No. 4,490,963 to Knudsen (the "Knudsen" reference) and United States Patent No. 4,834,264 to Siegel (the "Siegel" reference). In the final office action, the Examiner has again rightfully recognized the deficiency of the Knudsen reference in that at the very least it fails to disclose dispensing one or more products from a plurality of different drug sources into a common funnel and effecting relative motion between the funnel and a plurality of product package template cavities. Applicant completely agrees with the deficiencies of the art identified by the Examiner.

In order to overcome this deficiency, the Examiner cites the teachings of the Siegel reference and particularly Figure 2. Applicant agrees with the Examiner's assessment that the Knudsen reference is deficient at the very least for the reasons cited by the Examiner. However, Applicant submits that the Siegel reference similarly fails to provide the requisite teaching or suggestion that renders Applicant's claimed invention invalid as being obvious in light of the cited art. The applicable standard requires that there be some specific teaching or suggestion in the prior art regarding the recognized deficiency.

However, an examination of the reference and, particularly, the cited portions set forth by the Examiner confirms that the combination of references remains deficient and cannot support the Examiner's claim rejections. In support of the Examiner's position, the Examiner has asserted that Figure 2 of the Siegel reference discloses a funnel over individual ones of the cavities and effecting motion in at least two directions between the funnel and

plurality of product package template cavities. However, Applicant submits that this is incorrect because the Siegel reference does not teach dispensing one or more products from a plurality of drug sources into a common funnel and effecting relative motion between the single funnel and a plurality of product package template cavities.

Rather, the Siegel reference is merely directed to a dispensing apparatus with a hopper including a support frame and a collar mounted on the frame as well as a stirring mechanism to agitate the pharmaceutical products. More specifically, in Siegel, a single supply of material such as tablets is placed within the hopper and agitated so that the material will pass into a separating aperture or separator plate that includes a plurality of apertures corresponding to the cavities of a solid pharmaceutical product package that is to be filled. See Column 3, lines 8-45. The tablets fill individual cavities in the separator plate and the stirring mechanism is utilized to ensure that all the cavities in the separator plate are temporarily filled. Through the relative motion of the plates with cavities and/or holes, a single blister package may be simultaneously filled with multiple individual pharmaceutical products.

In Siegel, if there are funnels at all, there are a plurality, each of which are directly aligned over a corresponding cavity. This is in sharp contrast with the Applicant's presently claimed invention, which seeks to alleviate such existing limitations and provide a system which selectively dispenses one or more solid pharmaceutical products from a plurality of different drug sources into a common funnel.

The Siegel reference simply cannot be used to place multiple different solid pharmaceutical products into individual cavities unless the overall filling process is repeated with a different pharmaceutical product. However, this significantly increases the

inefficiency of the system where multiple different pharmaceutical products must be added. Moreover, even if this were to occur, every cavity would have the same number of different products. This process contrasts sharply with Applicant's presently disclosed invention wherein the system automatically selectively dispenses one or more pharmaceutical products from a plurality of drug sources into a common funnel and effectuates relative motion between the funnel and plurality of product package template cavities to selectively locate the funnel over individual ones of the cavities. Indeed the combination of Knudsen and Siegel would not result in the specific innovations disclosed and claimed by the Applicant in the present application. Moreover, significantly, the combination of Knudsen and Siegel also simply would not result in the advantages of the present invention.

C. The Cited References, U.S. Patent Nos. 4,490,963, 4,834,264, and 6,023,916, Fail to Teach or Suggest the Claimed Invention.

Dependent claims 11 and 12 stand rejected as being obvious in light of the combined teachings of United States Patent No. 4,490,963 to Knudsen, United States Patent No. 4,834,264 to Siegel, and United States Patent No. 6,023,91 to Bouthiette. In the final office action, the Examiner correctly concluded that Knudsen failed to disclose the step of dispensing first and second pharmaceuticals into a single template cavity. Applicant completely agrees with the deficiencies of the art identified by the Examiner. However, the Examiner incorrectly asserts that Bouthiette discloses disclosing first and second pharmaceuticals into a single template cavity. Applicant submits that the combination of references fails to teach or suggest Applicant's claimed invention.

The Bouthiette reference related to manual manipulation of solid pharmaceuticals for placement into the product package. In addition, along with the other references, Bouthiette fails to teach or suggest the claimed relative motion between a common funnel and a plurality

of package template cavities. There is simply no description whatsoever regarding a funnel let alone automated motion of a funnel with respect to product cavities or templates.

Finally, since claims 11 and 12 depend from independent claim 7, claims 11 and 12 are not obvious in light of the references because claims 7 is not obvious in light of the references as discussed above. Accordingly, Applicant submits that the claims are allowable over the cited prior art.

IX CONCLUSION

In summary, the Applicant submits that neither the combination of Knudsen and Siegel nor any of the remaining references would result in Applicant's presently claimed invention. In light of the foregoing, Applicant respectfully requests that the Examiner withdraw the rejections and allow all of the claims in the application.

Respectfully submitted,

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CLAIMS ON APPEAL:

1. (Canceled)

2. (Canceled)

3. (Canceled)

4. (Canceled)

5. (Canceled)

6. (Canceled)

7. (Previously Presented) A method of filling solid pharmaceutical product packaging comprising the steps of:

automatically selectively dispensing one or more solid pharmaceutical products from a plurality of different drug sources into a common funnel and effecting relative motion in at least two directions between the funnel and plurality of product package template cavities to selectively locate the funnel over individual ones of the cavities in order to place one or more solid pharmaceutical products from the plurality of different drug sources into each of said plurality of template cavities; and

thereafter automatically transferring the solid pharmaceuticals located in the plurality of product package template cavities into corresponding cavities of the product package member.

8. (Previously Presented) The method of claim 7, further comprising a step of, during said step of selectively dispensing the solid pharmaceutical products, simultaneously sealing another pharmaceutical product package that has been previously filled with a variety of solid pharmaceuticals.

9. (Previously Presented) The method of claim 7, further comprising a step of printing information on a pharmaceutical product package.

10. (Previously Presented) The method of claim 8, further comprising a step of printing information on a pharmaceutical product package.

11. (Previously Presented) The method of claim 7, further comprising a step of at least substantially simultaneously dispensing first and second pharmaceuticals from first and second canisters into a single template cavity.

12. (Previously Presented) The method of claim 8, further comprising a step of at least substantially simultaneously dispensing first and second pharmaceuticals from first and second canisters into a single template cavity.

13. (Previously Presented) The method of claim 7, wherein the step of effecting relative motion comprises moving the product package template cavities beneath the funnel such that each of the desired template cavities is placed beneath the funnel.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail on June 29, 2004 in an envelope addressed to:

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